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Patent

Attorney's Docket No. 033303-012

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In Patent Application of: | ) | |
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| Prem S. PAUL et al. | ) | Group Art Unit: 1645 |
| | ) | |
| Serial No.: 09/810,501 | ) | Examiner: D. Wortman |
| | ) | |
| Filed: March 19, 2001 | ) | Confirmation No.: 1105 |
| | ) | |
| For: POLYNUCLEIC ACIDS ISOLATED FROM A PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME VIRUS (PRRSV), PROTEINS ENCODED BY THE POLYNUCLEIC ACIDS, VACCINES BASED ON THE PROTEINS AND/OR POLYNUCLEIC ACIDS, A METHOD OF PROTECTING A PIG FROM A PRRSV AND A METHOD OF DETECTING A PRRSV | ) | |

**REPLY TO REQUIREMENT FOR RESTRICTION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Official Action issued May 6, 2002, Applicants hereby elect, albeit with traverse, the Group V "invention" which includes Claims 30 and 31, drawn to kits and DNA methods.

The Restriction Requirement is traversed because it is believed that the six groups of claims set up by the Examiner are drawn to sufficiently interrelated inventions to warrant examination thereof in a single application. A complete search for all groups of claims

would be coextensive such that search and examination of the entire application can be made without serious burden on the U.S. Patent and Trademark Office.

Restriction is applicable only to independent and distinct inventions (35 U.S.C. § 121). The term "independent" means not dependent, and the term "distinct" means that two or more subjects are patentable (novel and unobvious) over each other (M.P.E.P. 802.01). The burden is on the Examiner to provide reasons and/or examples in support of restriction (M.P.E.P. 803).

Applicants respectfully traverse the restriction requirement on the ground that the reasons and/or examples provided in the Restriction Requirement of May 6, 2002 do not adequately support restriction. Consequently, the restriction requirement is improper, and should be withdrawn.

For example, the Examiner has not explained how Group I, which includes claims directed to DNA, and Group V, drawn to kits and DNA methods, are independent and distinct. The Examiner has not explained how Group III, directed to antibodies and vaccines, and Group IV, directed to antibodies, kits, and method of detection, are independent and distinct.

It is believed that the standards of novelty and unobviousness conflict with reasoning which considers an invention independent and distinct from itself. Therefore, the reasons and/or examples in support of restriction between Groups III and IV, set forth in the Restriction Requirement of May 6, 2002 do not meet the requirements of 35 U.S.C.

§ 121. As a result, the restriction is improper, and should be withdrawn, or at last modified.

Moreover, although the claimed peptide and polynucleotide structures are different, the peptides of Group II are encoded by the DNA of Group I. The Official Action of May 6, 2002 does not explain how these claimed structures are independent and distinct from each other.

Furthermore, viruses are generally known to contain both peptides and polynucleotides. Thus, the Restriction Requirement does not explain how the claimed virus is independent and distinct from the claimed polynucleotides. Accordingly, the reasons and/or examples in support of restriction between the claimed virus (Group VI) and the claimed DNA (Group I) and peptides (Group II) on the basis of differences in structure fail to meet the explicit requirements of 35 U.S.C. § 121.

Applicants note that the Restriction Requirement of May 6, 2002 appears to imply that the claimed polynucleotide is limited to DNA. The term "polynucleic acid" can also refer to RNA. Thus, the reasons and/or examples provided in support of restriction between the protein and virus of Groups II and VI and the polynucleotide of Group I are not entirely accurate, and cannot properly support restriction between these groups.

With regard to different methods of making the peptides and virus of Groups II and VI and the polynucleotide of Group I, it is not known how any organism, including a virus, can be reproduced or made in the absence of polynucleotides. Furthermore, the

mere assertion that different methods exist for making polypeptides and polynucleotides does not explain how the claimed proteins and the claimed polynucleotides are independent and distinct from the claimed polynucleotides. By this logic, the mere existence of more than one method of making an object would render the object restrictable from and patentable over itself.

Accordingly, the reasons and/or examples in support of restriction between the peptides and virus of Groups II and VI and the polynucleotide of Group I fail to meet the explicit requirements of 35 U.S.C. § 121. Therefore, restriction between the protein and virus of Groups II and VI and the polynucleotide of Group I is improper, and should be withdrawn.

The polypeptide and virus of Groups II and VI have been distinguished from the antibody of Groups III and IV on the basis of their different structures and biological properties.

No evidence is provided in the Official Action of May 6, 2002 to support these assertions. As a result, the reasons and/or examples in support of restriction between the polypeptide and virus of Groups II and VI and the antibody of Groups III and IV on the basis of differing structures are unpersuasive, and fail to explain how the claimed protein and virus are independent and distinct from the claimed antibody.

Finally, the assertion that the polypeptide can be made by recombinant means or chemical synthesis has been provided. However, the relevance of methods for making a

polypeptide to restriction between a protein and an antibody is not apparent. For example, is it impossible for one to make an antibody by recombinant means or chemical synthesis? Further, does the mere existence of independent methods for making an object support restriction?

In view of the lack of explanations in the Official Action of May 6, 2002, the reasons and/or examples in support of restriction between the protein and virus of Groups II and VI and the antibody of Groups III and IV fail to meet the explicit requirements of 35 U.S.C. § 121. Therefore, restriction between the protein and virus of Groups II and VI and the antibody of Groups III and IV is improper, and should be withdrawn.

Groups I and VI have been related as process of use and product made. That the claimed DNA can be used to make proteins as well as virus does not support restriction, as these proteins are necessarily those expressed in the virus itself. Accordingly, the reason and/or example in support of restriction between Groups I and VI cannot properly support restriction.

Thus, the burden of providing reasons and/or examples in support of restriction between Groups I and VI has not been met. Accordingly, restriction between Groups I and VI is improper, and should be withdrawn.

The antibody of Groups III and IV and the polynucleotides of Group I are considered distinct since they have different structures and biological properties.

As explained above, mere differences in structure and properties are insufficient to meet the requirements of restriction under 35 U.S.C. § 121 in the absence of an explanation as to how the antibodies of Groups III or IV and the polynucleotides of Group I are distinct from each other.

Accordingly, the burden of providing reasons and/or examples in support of restriction between these groups has not been met. Therefore, restriction between the protein of Groups II, III and IV and the polynucleotide of Group I is improper, and should be withdrawn.

From the foregoing, substantive action on the merits of all of the claims of record is respectfully requested.

Re-examination and reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. §1.112 and §1.115 in light of the remarks which follow, are respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

If the Examiner has any questions concerning the amendment and response or the application in general, the Examiner is invited to contact the undersigned so as to expedite prosecution.

Respectfully submitted,

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